REMARKS

Entry of the amendment is requested.

The specification is amended, as is claim 58. The amendment is discussed infra.

The allowance of claims 13 and 92 is noted with appreciation. Claim 115 is objected to; however, it is believed the objection is in error.

According to the Examiner:

> "Three sequences of claim 115 are not identified by a SEQ ID NO. In addition there are sequences on pages 20-21 which do not have SEQ ID NOs."

Claim 115 reads:

> An isolated peptide consisting of the amino acid sequence LLSHGAVIEV (amino acids 158-167 of SEQ ID NO: 32) or SLSKILDTV (amino acids 960-968 of SEQ DI NO: 32), or SLDQKLFQL (amino acids 1318-1326 of SEQ ID NO: 32).

The claims refer to internal regions of a presented sequence.

According to the MPEP, 2422.03 (page 2400-35):

> "Sequence identifiers can also be used to discuss and/or claim parts or fragments of a property presented sequence. For example, language such as residues 14-243 of SEQ ID NO: 23 is permissible and the fragment need not be separately presented in the 'Sequence Listing.'"

Regarding the alleged lack of SEQ. ID. NOS. over pages 20-21, the Examiner is believed to be referring to paragraph [0084], which states, prior to the presentation of the listing:

> "The complete list of peptides tested, with reference to their position in SEQ ID NO: 23, follows."

It is believed that both claim 115 and the specification are in compliance with the sequence rules, as is evidence by the quoted section of the MPEP. As such, the objection should be withdrawn.

The Examiner has rejected claim 58 under 35 U.S.C. § 112, second paragraph, alleging that the language is unclear, and is open to 3 different interpretations.

Applicants do not agree, but have amended the claim in order to advance prosecution. With respect to the alleged meaning that the claim "reads on an exogenous amino acid sequence inserted into the amino acid sequence of the isolated cancer associated antigens," applicants do not see how the Examiner arrived at this interpretation. Claim 58 depends from claim 13, which specifically recites specific sequences. The claim is not open to this interpretation. Nor do applicants see the validity of the interpretation that the claim reads on "a peptide fragment of the isolated cancer associated antigen inserted into the isolated cancer associated antigen." Should the Examiner persist in maintaining this position, a much clearer, explicit discussion of why these interpretations are valid must be provided.

The Examiner dismisses applicants' argument that the language used was permitted in 6,830,924 by stating:

> "Each patent application is examined on its own merits," and
>
> "The claims of U.S. Patent No. 6,830,924 are not drawn to MHC binding peptides."

Both statements are true, but irrelevant. The statute, i.e., 35 U.S.C. § 112, second paragraph, is the same. The language employed in the claims is the same. Whether

language satisfies 35 U.S.C. § 112, second paragraph is not dependent upon what is or is not claimed. Further, the claims of 6,830,924 are not unrelated subject matter, as they are drawn to nucleic acid molecules encoding peptides of the type claimed here. Whether in the context of this application, or the issued patent, the peptide must be defined clearly, and in a way that satisfies 35 U.S.C. § 112, second paragraph. The language satisfied the statute during the pendency of the application which issued as the '924 patent. Applicants are unaware of any change in the statute. As such, the requisites of 35 U.S.C. § 112, second paragraph are met.

The Examiner has then rejected claims 58-60, 85, and 86, under 35 U.S.C. § 112, first paragraph. The rejection made in the previous Office Action is maintained. In the prior action, the Examiner stated, at the paragraph bridging pages 4-5:

> "However, the specification does [sic; not?] teach which fragment or derived peptides claimed in the instant claims can be used to stimulate immune response and binds to one or more MHC molecules presented on the surface of cells and elicit a cytolytic response. It is not clear if (CTLs) could be generated using any peptide fragment of SEQ ID NO: 32 other than peptides LLSHGAVIEV, SLSKILDTV and SLDQKLFQL."

The final rejection repeats this position, and applicants traverse.

First, applicants point out that the order presented by the Examiner with respect to peptide activity is backwards. Peptides bind to MHC molecules first and then may stimulate T cells. Applicants will discuss this and phenomena infra.

They first point out, however, that NONE of the claims under rejection require stimulation of CTLs. Claims 58-60 require MHC binding only. Claims 85 and 86 do not require this at all.

The Examiner cannot read language into the claims that is not present. Rather, the Examiner must consider the claims as written. Hence, the discussion of issues regarding T cell stimulation is misplaced. There is no such requirement in any claim. The only issues which should be under consideration are those which relate to actual claim language, not language imported into the claims. The Examiner does not appear to dispute, for example, that the specification does teach how to determine MHC binding. The only rejections have been premised on an alleged failure to show CTL stimulation.

On this second point, however, even if one could impute language to the claims, the rejection cannot be maintained.

It is agreed, as the Examiner states, that "the number of peptide fragments greater than 8 or 9 amino acids that could be generated from SEQ ID NO: 32 is enormous."

This is irrelevant.

> "The mere fact that experimentation may be have difficult and time consuming does not mandate a conclusion that such experimentation would have been considered to be 'undue' in this art."

Falkner v. Ingles, 79 USPQ 2d 1001, 1019 (Fed. Cir. 2006).

The specification describes precisely how one could determine which peptide fragment of SEQ ID NO: 32 (or any SEQ ID), bind to MHC molecules, and then to determine if CTLs are generated, and if these lyse cancer cells. See, Example 21, e.g., at pages 19-20. Peptide synthesis is discussed. SO, too, is an ELISPOT assay, which is described in great detail. The ELISPOT assay is a well known, standard feature of molecular biology.

It is agreed that finding peptides that stimulate CTLs is not a trivial matter; however, the fact is that the inventors, Wang, and many others, have identified such

peptides. It can hardly be said that because an experiment is difficult, or time consuming, that this rises to the level of undue experimentation, which must be shown to overcome the presumption of enablement. As such, the rejection should be withdrawn.

The Examiner has also rejected claims 58-60, 85, and 86 under 35 U.S.C. § 112, first paragraph, for failing to satisfy the written description requirement. Applicants have considered the rejection carefully, and traverse.

Again, applicants agree with the Examiner that there are many peptides which satisfy the ambit of the claims; however, the fact that a claim is broad does not mean it does not satisfy the written description requirement. Ab initio, one must address this question: could one present a list of all peptides which satisfy the claim? The answer is yes.

The Examiner then proceeds, however, to discuss how applicants have shown that 3 peptides both bind to an MHC molecule and stimulate CTLs. Yet again, the Examiner errs by reading language into the claims that is not present. The Examiner goes on to compound the error by stating that "a sufficient number" of representative peptides has not been described.

It is submitted that there are no numerical values that can be used to establish the fictive "representative number" of examples. This is not a requirement of the law.

The Examiner then goes on to discuss how applicants have not defined a connection between structure and function so as to satisfy the written description requirement.

Falkner v. Ingles, cited supra, makes clear that the Federal Circuit has repudiated this approach. As stated in Falkner, at 1321:

> "(T)here is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure."

Indeed, Falkner makes clear that exemplification and reduction of practice are not necessary either. Falkner at 1321. Hence, given that there is a reference sequence in the specification, recited in the claims, and a molecule length is set forth, the Examiner's position is contrary to the law, and the rejection should be withdrawn.

In view of the foregoing, withdrawal of the rejections of claims 58-60, 85, and 86 is believed proper and should be withdrawn. Similarly, the objection to claim 115 is improper and should be withdrawn.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-0624, under Order No. NY-LUD 5793-US1-CIP (10315551) from which the undersigned is authorized to draw.

Dated:

Respectfully submitted,

By _____

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